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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 09/207,161 | 12/07/98 | HILLMAN J | PF-0208-1DIV |

| EXAMINER | |
|---|---|
| CARLSON, K | |
| **ART UNIT** | **PAPER NUMBER** |
| 1653 | 21 |

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LEGAL DEPARTMENT
INCYTE GENOMICS INC
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**DATE MAILED:** 03/29/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

| Advisory Action | Application No. 09/207,161 | Applicant(s) HILLMAN ET AL. | |
|---|---|---|---|
| | Examiner Karen Cochrane Carlson, Ph.D. | Art Unit 1653 | |

*--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

THE REPLY FILED 27 February 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check only a) or b)]

a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.

b) ☒ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 707.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on *December 28, 2000*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.

3. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search. (see NOTE below);

   (b) ☐ they raise the issue of new matter. (see Note below);

   (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*.

4. ☒ Applicant's reply has overcome the following rejection(s): *See Continuation Sheet*.

5. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

6. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *1 and 11*.

   Claim(s) withdrawn from consideration: *12-20*.

9. ☐ The proposed drawing correction filed on _____ a)☐ has b)☐ has not been approved by the Examiner.

10. ☐ Note the attached Information Disclosure Statement(s)( PTO-1449) Paper No(s). _____.

11. ☐ Other:

Continuation of 3. NOTE: The recitation of "15 amino acids" would have to be addressed, the new claims would have to be rejected.

Continuation of 4. Applicant's reply has overcome the following rejection(s): if entered, the rejection under 35 USC 102(a) would have been overcome..

Continuation of 6. does NOT place the application in condition for allowance because: Applicants argument that the final rejection was improper because there was a new ground of rejection under 35 USC 102 when the rejection was changed from paragraph b to paragraph a. This argument is not persuasive because the rejection is still under 35 USC 102 and Applicants did not overcome the rejection whether it was made under paragraph b or paragraph a. Therefore, the prosecution was not materially affected by that change in paragraph used to reject the claimed invention and the claims stand finally rejected for reasons of record.

Applicants contend that there are no new issues raised by the inclusion of the phrase "at least 15 contiguous amino acids" because they had addressed this issue in their previous after-final response and the Examiner had commented on this phrase in the final rejection at page 7. This phrase was brought into the claims after-final. The Examiner's comments in the final office actions was "Applicants argue that Deleersnijder et al. do not teach 15 consecutive amino acids in SEQ ID NO:1. The claims do not require 15 consecutive amino acids. Therefore, this argument is not persuasive". It is clear that 15 amino acids within SEQ ID NO:1 was not examined, because this limitation was not present in the claims until after final rejection. While Deleersnijder et al. may be overcome by this limitation, other rejections under 35 USC 101 and 112, first paragraph addressing this limitation would have to be made. Therefore, this argument is not persuasive.

Applicants urge that this is the era of the "caring and sharing" Patent Office of the new millennium and that the use of gamesmanship by Patent Office employees via strained and onerous interpretation of Patent Office rules does not fit into the mission of providing beneficial customer service. While the Examiner is warmed by the thought of working in such a hospitable environment and the fact that this hospitable environment is being noted by our customers, the instant invention still lacks utility, enablment, and written description for reasons of record. Applicants have not pointed out where the Examiner's strained and onerous interpretation of the Patent Office rules have been applied in the rejections at hand. Therefore, because Applicants comments center on their view that the guidelines are flawed, not that the Examiner has erred in applying the guidelines, no "gamesmanship" is being played by this Examiner to deny Applicants a patent.

Applicants have not provided any new arguments against the rejections under 35 USC 101 and 112, as Applicants admit on page 5, para. 4. Applicants note that the Examiner has not addressed Applicants legal arguments regarding the guidlelines is correct. It is not the Examiner's place to criticize the guidlelines, but rather to support the guidelines provided as being consonant with the statutes. As noted in the rejections, Applicants do not have IMP-2 in hand - and therefore do not have a composition of matter - and Applicants do not know what the function of IMP-2 is. Therefore, use of the protein to detect claimed sequences via hybridization is not a specific utility for the protein on its face and finding sequences that have no known function is not substantial. If one skilled in the art doesn't know what the function of a protein is, and the protein is not in hand, then clearly there can be no real-world use for the protein.

Applicants argue that their specification describes the biolgically active and immunologically active fragments of the protein as well as variants thereof. If the biological activity of IMP-2 is not known, then how can one skilled in the art know what a biolgically active fragment of this protein is when the activity cannot be tested? This is the same reasoning for immunologically active fragment of IMP-2 and variants of IMP-2. Applicants should not receive a patent on a molecule having no known function, and that is not in hand. These rejections under 35 USC 112 is consistent with case law, and the guidelines (see examples 13 and 14). The courts stated in In re Gardner (166 USPQ 138) that the law requires that the disclosure in an application shall inform those skilled in the art how to use applicant's alleged discovery, not how to find out how to use it for themselves.

The Examiner believes that all pertinent arguments have been addressed.

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER